

510(k) Summary according to 807.92(c)
TowerLOX Pedicle Screw System

OCT 16 2012

Date: September 17, 2012

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Trade Name: TowerLOX Pedicle Screw System
Product Class: Class II
Classification: 888.3070 Pedicle Screw Spinal System
Product Codes: MNI, MNH
Panel Code: 87

Predicate Device(s): CapLOX II Pedicle Screw System (K111115, SE 9-13-11),
(K120292, SE 4-13-12)
Laguna Pedicle Screw System (K103748, SE 3-2-11)
Denali Spinal System (K042635, SE 1-10-05)
Spherx Pedicle Screw System (K092287, SE 10-6-09)
Sextant/CD Horizon MIS System (K121680, SE 7-5-12)
Array Spinal System (K061978, SE 8-11-06)

Reason for this Submission: This Special 510(k) involves several changes to the previously cleared CapLOX II System that allow for:

- 1. Several dimensional changes
- 2. New instrumentation added to the set configuration
- 3. New surgical technique developed for set to incorporate instrumentation for minimally invasive surgical technique.
- 4. Rod design with tip feature that allows for minimally invasive delivery and control, and
- 5. Add implant screw lengths now offering 60-100mm in 5mm increments on select diameters

Indications for Use/Intended Use: The TowerLOX Spinal System is a posterior, non-cervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and

sacral spine including degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

In addition, when used as a pedicle screw fixation system, the TowerLOX Spinal System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral, L5-S1 vertebra, who are receiving fusion by autogenous bone graft only, who are having the device attached to the lumbar and sacral spine (levels may be from L3 to the sacrum/ilium), who are having the device removed after the attainment of a solid fusion.

Device Description: The TowerLOX Pedicle Screw System is an implant device made from a titanium alloy TI 6AL4V-ELI. It is to be implanted from the posterior approach. The screws are available in diameters from 4.9-8.0mm and in lengths from 30-100mm. Rods are available in 5.5mm diameter, as either straight rods available in lengths from 30-500mm or pre-curved rods available in lengths from 30-120mm. The system includes a set screw, tulip heads, and a cap to complete the assembly of the implant. The system also includes all necessary instrumentation for a minimally invasive surgical technique

Performance Testing: This Special 510(k) involved changes that did not alter the mechanical function of the system; so no additional performance testing was conducted.

Conclusion: Captiva Spine concludes that the changes to the system do not introduce any new risks and therefore, the system is Substantially Equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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OCT 16 2012

Re: K122332

Trade/Device Name: TowerLOX Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH
Dated: September 19, 2012
Received: September 20, 2012

Dear Dr. Jansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

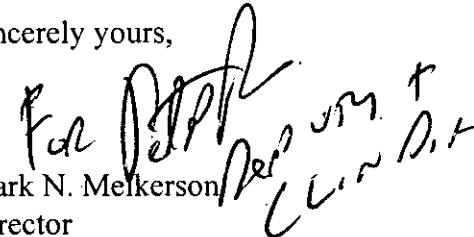
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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K122332

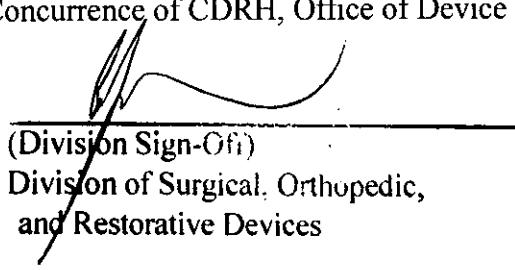
The TowerLOX Spinal System is a posterior, non-cervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine including degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudoarthrosis and failed previous fusion.

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122332